# HAZARDOUS WASTE PHARMACEUTICALS FINAL RULE

FEDERAL ENVIRONMENTAL SYMPOSIUM

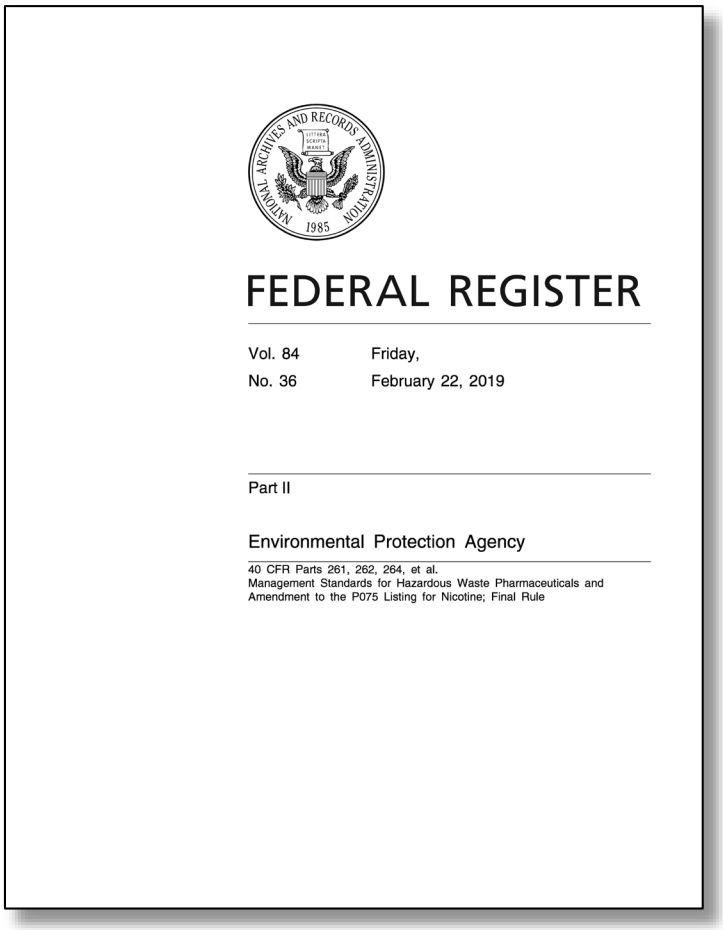
OCTOBER 31, 2019

## Introduction to the Final Rule

Kristin Fitzgerald, EPA
Brian Knieser, EPA
Laura Stanley, EPA

# FEDERAL REGISTER PUBLICATION

- RCRA Hazardous Waste Pharmaceuticals Final Rule
- The final rule was published in the Federal Register on February 22, 2019
- 84 FR 5816
- Amends 40 CFR Parts 261 & 266
- https://www.govinfo.gov/content/pkg/FR-2019-02-22/pdf/2019-01298.pdf



FEDERAL REGISTER

Vol. 84 Friday,
No. 36 February 22, 2019

Part II

Environmental Protection Agency

40 CFR Parts 261, 262, 264, et al.
Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine; Final Rule

# 40 CFR - PROTECTION OF THE ENVIRONMENT

- Part 260 – Definitions, etc.
- **Part 261 – Definition of solid and hazardous waste**

  ***The final rule amends the nicotine listing in 261***
- Part 262 – Generator regulations (VSQG, SQG, LQG)
- Part 263 – HW Transporters
- Part 264 – Permitted TSDFs
- Part 265 – Interim Status TSDFs
- **Part 266 – Standards for specific hazardous wastes/facilities**

  ***The final rule adds new Subpart P to Part 266***

# OUTLINE

1. Effective Dates & State Adoption
2. Pharmaceuticals that are Hazardous Waste
3. Amendment of the Nicotine Listing in Part 261
4. Part 266 Subpart P Overview

# I. EFFECTIVE DATES & STATE ADOPTION

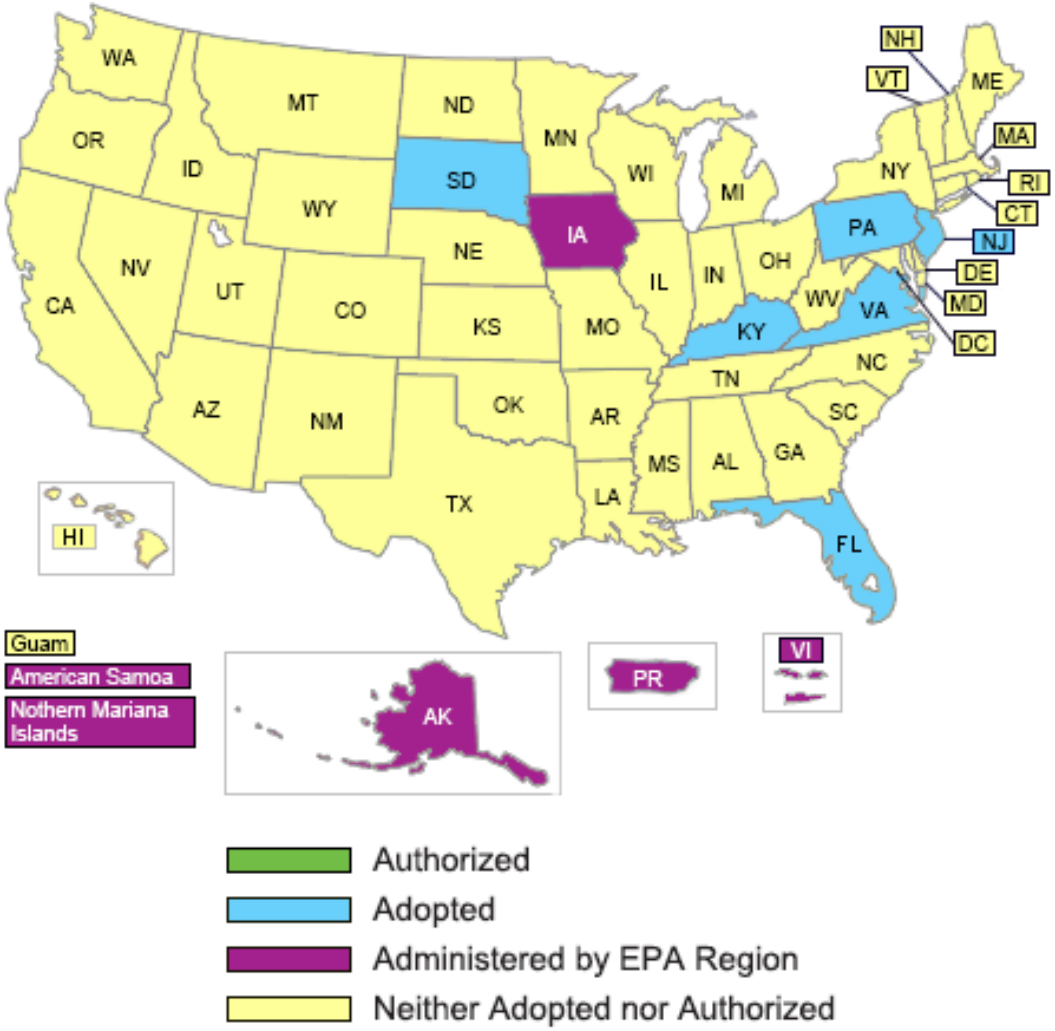
§ 266.500

# EFFECTIVE DATE – SUBPART P & NICOTINE

- The effective date of Subpart P and the nicotine amendment is August 21, 2019 in:
  - Non-authorized States: Iowa, Alaska
  - Indian Country
  - US Territories (except Guam)
- Subpart P and nicotine amendment are not effective in authorized states until state adopts the new rules
- Authorized states must adopt Subpart P
- Authorized states are not required to adopt the nicotine amendment
- The sewer ban was effective in all states on August 21, 2019

# STATE ADOPTION OF PART 266 SUBPART P

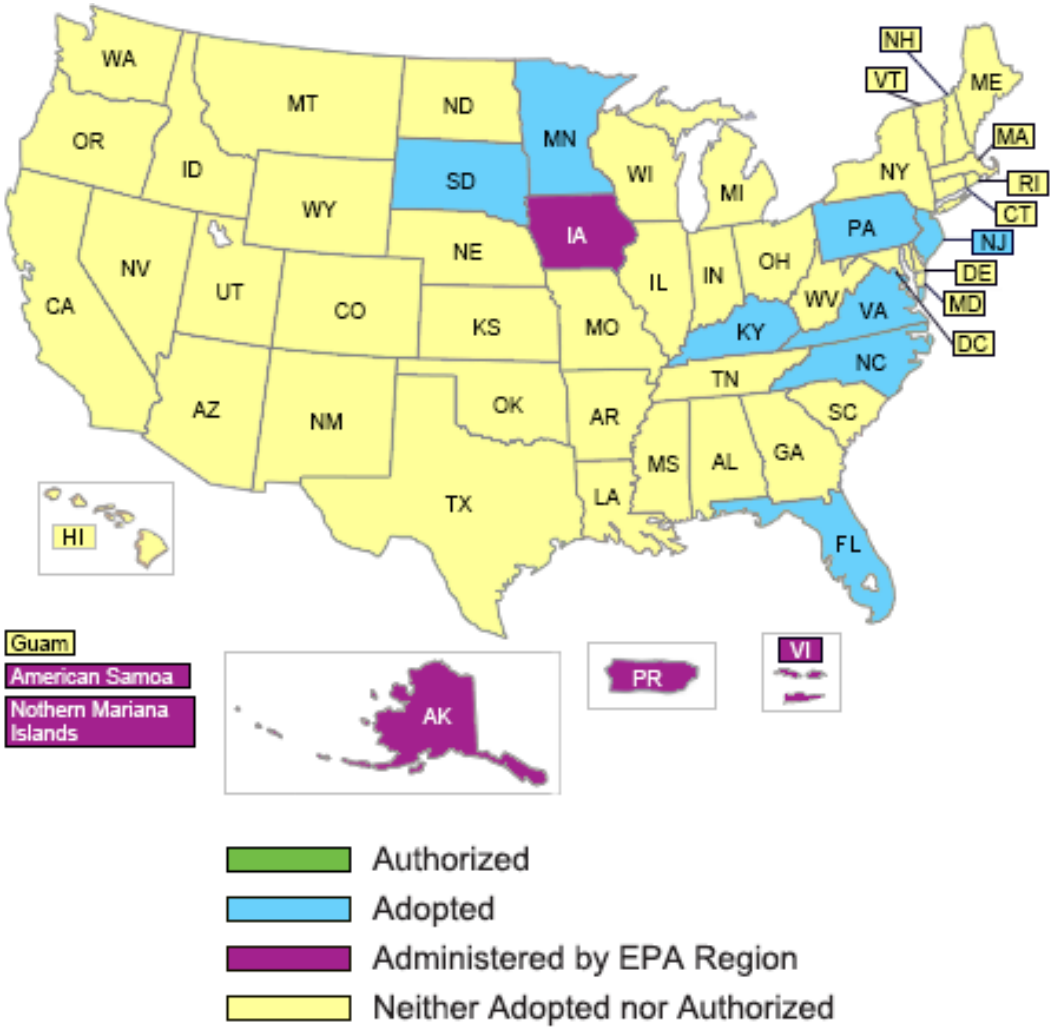
<u>Effective in:</u>
Indian Country
4 Territories
8 States




As of Sept 6, 2019

# STATE ADOPTION OF NICOTINE AMENDMENT

<u>Effective in:</u>
Indian Country
4 Territories
10 States




As of Sept 6, 2019

# II. PHARMACEUTICALS THAT ARE HW

# WASTES NOT COVERED BY THIS RCRA RULE

- Pharmaceuticals discarded at your home (aka household hazardous waste)
  - EPA encourages participation in pharmaceutical take-backs to dispose of unused leftover medications
- Medical waste


Different terms for the same waste:

- Medical Waste
- Regulated Medical Waste
- Biohazardous Waste
- Infectious Waste
- Red Bag Waste

# MEDICAL WASTE VS HAZARDOUS WASTE

Medical Waste is Different than RCRA Hazardous Waste

- Disposal of medical waste is NOT regulated by EPA as RCRA hazardous waste
- Disposal of medical waste is regulated by states

# WHICH PHARMACEUTICALS ARE HW?

- There is no (free) definitive list of all pharmaceuticals that are HW

- A few sources to use:

  https://www.epa.gov/hwgenerators/archive-hazardous-waste-pharmaceuticals-wiki

  http://www.hercenter.org/hazmat/pharma.cfm

  http://www.hercenter.org/hazmat/tenstepblueprint.pdf

  https://www.colorado.gov/pacific/sites/default/files/HM_mw-examples-of-hw-pharmaceuticals.pdf

  https://floridadep.gov/sites/default/files/Hazardous_Waste_Pharm_List_Feb17.pdf

# EXAMPLES OF LISTED HW PHARMACEUTICALS

- P-listed ACUTE hazardous wastes
  - Warfarin (P001)
  - Arsenic Trioxide (P012)
  - Nicotine (P075)
  - Physostigmine salicylate (P188)
  - Physostigmine (P204)
- U-listed hazardous wastes
  - Mitomycin C (U010)
  - Chloral hydrate (U034)
  - Cyclophosphamide (U058)
  - Lindane (U129)
  - Selenium sulfide (U205)

# EXAMPLES OF CHARACTERISTIC PHARMACEUTICALS

- Ignitable (D001):
  - Preparations with alcohol

- Toxicity (D004-D043): if present above certain concentrations in the leachate during TCLP test
  - Chromium (multi-vitamins)
  - m-Cresol (preservative in insulin)
  - Mercury (preservative thimerosal)
  - Selenium (multi-vitamins, dandruff shampoos)
  - Silver (burn creams)

# III. AMENDMENT OF NICOTINE LISTING

# AMENDMENT OF THE NICOTINE LISTING

- The P075 listing for nicotine is being amended such that FDA-approved over-the-counter nicotine replacement therapies will no longer be included under the P075 listing for hazardous waste
  - EPA has concluded that nicotine <u>patches, gums and lozenges</u> do not meet the regulatory criteria for acute hazardous waste
  - Nicotine patches, gums and lozenges can be discarded as non-hazardous waste




≠ P075

# NICOTINE IS STILL LISTED AS P075

- Nicotine continues to be a listed, acute hazardous waste with the hazardous waste code P075
- Other unused formulations of nicotine will still be considered P075 when discarded, including
  - E-liquids/e-juices in e-cigarettes, cartridges, or vials
  - Prescription nicotine (e.g., nasal spray, inhaler)
  - Legacy pesticides containing nicotine
  - Nicotine used in research and manufacturing



= P075

# IV. OVERVIEW OF PART 266 SUBPART P

# OVERVIEW OF PART 266 SUBPART P

- Subpart P is a waste-specific and sector-specific final rule
  - for the management of hazardous waste pharmaceuticals
  - at healthcare facilities and reverse distributors
- These hazardous wastes and this sector are already regulated under RCRA
- We are not newly applying RCRA regulations to hazardous waste pharmaceuticals at healthcare facilities and reverse distributors
- We are changing HOW they are regulated under RCRA moving forward
  - GOAL: to create regulations that a better fit for the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors

§ 266.501

# PART 266 SUBPART P APPLICABILITY

- Part 266 Subpart P is considered more stringent, and therefore is NOT optional for
  - States to adopt
  - Healthcare facilities and reverse distributors
- Hazardous waste pharmaceuticals must be managed under Part 266 Subpart P by:
  - All reverse distributors
  - All healthcare facilities
    - IF healthcare facility generates above VSQG amounts of hazardous waste

# WASTE SPECIFIC & SECTOR SPECIFIC RULE

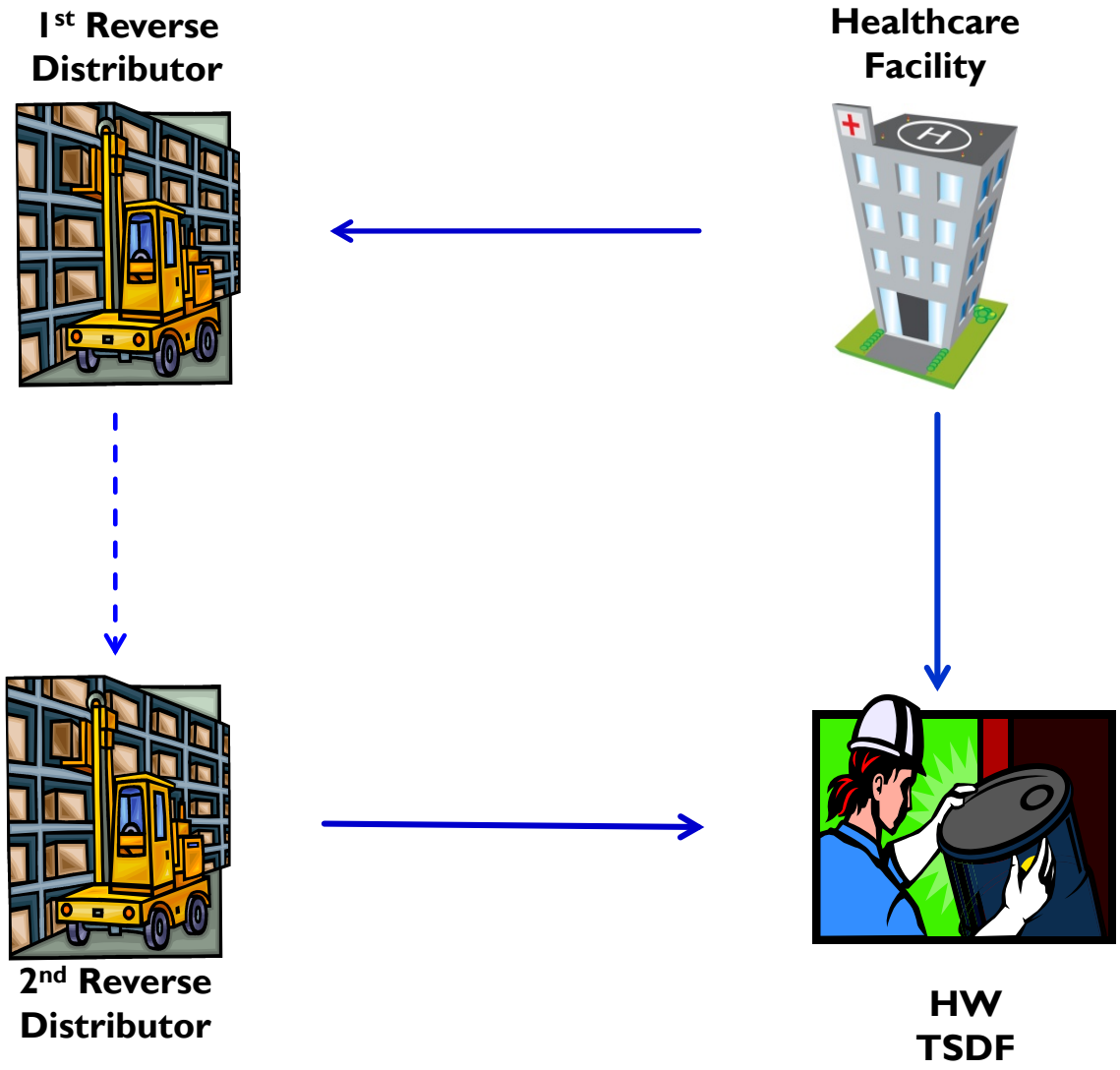
| | Hazardous Waste Pharmaceuticals | Other Hazardous Wastes |
|---|---|---|
| Healthcare facilities & reverse distributors | Part 266 Subpart P | • Part 262 (e.g., lab waste)<br>• Part 273 (universal waste)<br>• Part 279 (used oil)<br>• Etc. |
| Other facilities (e.g., farms/ranches, reverse logistics centers, manufacturers) | Part 262 | • Part 262<br>• Part 273 (universal waste)<br>• Part 279 (used oil)<br>• Etc. |

# FRAMEWORK OF PART 266 SUBPART P

How hazardous waste pharmaceuticals are regulated under Part 266 Subpart P depends on two things:

1. Who is managing the hazardous waste pharmaceuticals
   - Healthcare facility
   - Reverse distributor
2. Where the hazardous waste pharmaceuticals are headed
   - Directly to a TSDF
     - More traditional regulatory approach
   - Indirectly to a TSDF, via a reverse distributor to obtain manufacturer credit
     - The fact that the hazardous waste pharmaceuticals have **value** in the form of manufacturer credit has allowed us to take a tailored and more flexible regulatory approach

# Who Manages HW Pharmaceuticals?



# WHAT IS A HEALTHCARE FACILITY?

*Healthcare Facility* includes, but is not limited to:

- Wholesale distributors
- Third-party logistics providers (3PLs) that serve as forward distributors
- Military medical logistics facilities
- Hospitals
- Psychiatric hospitals
- Ambulatory surgical centers
- Health clinics
- Physicians' offices
- Optical and dental providers
- Chiropractors
- Long-term care facilities
- Ambulance services
- Pharmacies
- Long-term care pharmacies
- Mail-order pharmacies
- Retailers of pharmaceuticals (includes vape shops)
- Veterinary clinics & hospitals
- Co-located healthcare facilities (e.g. clinic at a manufacturer)

*Healthcare Facility* does NOT include:

- Pharmaceutical manufacturers
- Reverse distributors
- Reveres logistics centers

# WHAT IS A REVERSE DISTRIBUTOR?

- Reverse distributors are middlemen that provide manufacturer credit to healthcare facilities for unsold pharmaceuticals
- Under Subpart P, a reverse distributor is a new type of hazardous waste management facility that can accept hazardous waste from off-site
  - Can accept only hazardous waste that is "potentially creditable hazardous waste pharmaceutical" that has a reasonable expectation of receiving manufacturer credit
  - Can not accept other hazardous waste, including other types of hazardous waste pharmaceuticals
  - No RCRA storage permit required
  - Must comply with new regulations that are similar to LQG regulations, with some additions
  - All reverse distributors are regulated the same for hazardous waste pharmaceuticals (no VSQG, SQG, LQG categories)

# EPA VS DEA REVERSE DISTRIBUTOR

Issuing Manufacturer Credit Only

- DEA registrant
- DEA Reverse Distributor
- EPA/RCRA Reverse Distributor

Destroying (Treating) Pharmaceuticals

- DEA registrant
- DEA Reverse Distributor
- EPA/RCRA TSDF

§ 266.500

# TYPES OF HAZ WASTE PHARMACEUTICALS

There are 3 types of *Hazardous Waste Pharmaceuticals:*

1. Non-creditable hazardous waste pharmaceutical
2. Potentially creditable hazardous waste pharmaceutical
3. Evaluated hazardous waste pharmaceutical

# 3 Types of HW Pharmaceuticals

**Healthcare Facility**

**HW TSDF**

1. **Non-Creditable**
   - Broken or leaking
   - Repackaged
   - Dispensed
   - Expired >1 yr
   - Investigational new drugs
   - Contaminated PPE
   - Floor sweepings
   - Clean-up material

# 3 Types of HW Pharmaceuticals

1st Reverse Distributor

**2. Potentially Creditable**

- Original manufacturer packaging (except recalls)
- Undispensed
- Unexpired or less than 1-yr past expiration
- Reasonable expectation of receiving manufacturer credit

Healthcare Facility

**2. Potentially Creditable**

2nd Reverse Distributor

1. Non-Creditable

**HW TSDF**

# 3 Types of HW Pharmaceuticals

**1st Reverse Distributor**

2. Potentially Creditable

**Healthcare Facility**

2. Potentially Creditable

1. Non-Creditable

**2nd Reverse Distributor**

**3. Evaluated**

No further evaluation or verification of manufacturer credit is necessary

**HW TSDF**

# 3 Types of HW Pharmaceuticals

**1st Reverse Distributor**

2. Potentially Creditable

Tracking of Shipments Required

**Healthcare Facility**

2. Potentially Creditable

Tracking of Shipments Required

1. Non-Creditable

"Universal Waste Plus"

**2nd Reverse Distributor**

3. Evaluated

"LQG Plus"

**HW TSDF**

# DOES SUBPART P APPLY TO MY HEALTHCARE FACILITY?

Determining whether a healthcare facility is subject to Subpart P:

1. Count all hazardous waste generated per month, including hazardous waste pharmaceuticals
2. If generating below all monthly VSQG amounts of hazardous waste:
   - ≤1 kg (2.2 lbs) acute hazardous waste and
   - ≤ 100 kg (220 lbs) non-acute hazardous waste and
   - ≤ 100 kg (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste
3. Then:
   - Healthcare facility is not subject to Subpart P (VSQG healthcare facilities are subject to the sewer ban & empty container standards of Subpart P)
   - Healthcare facility is a VSQG under Part 262 for ALL of its hazardous waste

§ 266.504

# SUBPART P & VSQG HEALTHCARE FACILITIES

- Healthcare facilities that are "full VSQGs" are not subject to Subpart P, except the:
  - Sewer prohibition
  - New empty container provisions
- Healthcare facilities that are "full VSQGs" can choose to:
  - Opt into Part 266 Subpart P and comply with all of its provisions OR
  - Continue to operate under Part 262 and use none/any/all of the optional provisions in § 266.504
    - Using the optional provisions does not constitute "opting in" and does not require notification

# DOES SUBPART P APPLY TO MY HEALTHCARE FACILITY?

Determining whether a healthcare facility is subject to Subpart P:

1. Count all hazardous waste generated per month, including hazardous waste pharmaceuticals
2. If generate above any monthly VSQG amount of hazardous waste
   - >1 kg (2.2 lbs) acute hazardous waste or
   - >100 kg (220 lbs) non-acute hazardous waste or
   - >100 kg (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste
3. Then:
   - Healthcare facility is subject to Subpart P for its hazardous waste pharmaceuticals – and –
   - Healthcare is a VSQG/SQG/LQG under Part 262 for its other hazardous waste

§ 266.501

# GENERATOR CATEGORY & SUBPART P

- Once subject to Part 266 Subpart P
  - There are NO generator categories under Part 266 Subpart P
  - All healthcare facilities are regulated the same for their hazardous waste pharmaceuticals
  - All reverse distributors are regulated the same for their hazardous waste pharmaceuticals
  - Healthcare facilities & RDs operating under Subpart P do not have to
    - Keep track of how much hazardous waste pharmaceuticals they generate per month
    - Segregate the acute and non-acute hazardous waste pharmaceuticals
- Provides an incentive to over-manage non-hazardous pharmaceuticals as hazardous, without having to worry about bumping up generator category & incurring additional regulations

# HEALTHCARE FACILITY STANDARDS

- Under Subpart P, there are no
  - Satellite accumulation areas (SAAs)
  - Central accumulation areas (CAAs)
- At healthcare facilities it can be difficult to accumulate hazardous waste pharmaceuticals "at or near the point of generation" as is required by the SAA regulations
- Healthcare facilities can bring hazardous waste pharmaceuticals to a central accumulation area, but are not required to

§§ 266.502 and 266.503

# HEALTHCARE FACILITY STANDARDS

- Standards that apply to the healthcare facility
  - Notification
  - Training
  - Hazardous waste determination
- Other standards apply to the waste and differ depending on the type of hazardous waste pharmaceuticals

1. Non-creditable hazardous waste pharmaceuticals
   - destined for TSDF directly
   - regulations resemble Universal Waste but adds shipping requirements
2. Potentially creditable hazardous waste pharmaceuticals
   - destined indirectly to a TSDF via reverse distributor
   - regulations only for shipping

§§ 266.502 and 266.503

# HEALTHCARE FACILITY MANAGEMENT STANDARDS

1. Non-creditable hazardous waste pharmaceuticals:

- Labeling:
  - Accumulation containers must be labeled with the words "Hazardous Waste Pharmaceuticals"
  - No hazardous waste codes or other labeling requirements
- Container Standards:
  - Structurally sound, will not react with contents (i.e., compatible)
  - Remain closed and secured in a manner that prevents unauthorized access to its contents
- Accumulation time limit: 1 year

2. Potentially creditable hazardous waste pharmaceuticals:

- No labeling, containers standards or accumulation time

# MANAGE ALL PHARMACEUTICALS UNDER SUBPART P

- EPA encourages managing all waste pharmaceuticals under Subpart P
- Benefits of managing all waste pharmaceuticals under Subpart P
  - Less training: do not have to make individual hazardous waste determinations on each pharmaceutical
  - Fewer accumulation containers: can commingle hazardous and non-hazardous pharmaceuticals
  - Do not have to worry about bumping up in generator category: there are no generator categories under Subpart P

§ 266.505

# SEWER PROHIBITION

- Hazardous waste pharmaceuticals may not be sewered (e.g., no disposal down the drain and no flushing)
- Will prevent **1600 - 2300 tons** of hazardous waste pharmaceuticals from being sewered annually
- The sewer prohibition applies to
  - All healthcare facilities, including healthcare facilities that are VSQGs
  - All reverse distributors
- Hazardous wastes that are DEA controlled substances are also subject to the sewer prohibition
- We strongly discourage sewering of any pharmaceuticals by any entity
- NOTE: The sewer prohibition became **effective in ALL states on August 21, 2019** - regardless of whether the state is authorized to implement RCRA or has adopted Subpart P

§ 266.506

# DEA CONTROLLED SUBSTANCES

- Two new conditional exemptions for healthcare facilities and reverse distributors
  1. RCRA hazardous wastes that are also DEA controlled substances
  2. Household waste pharmaceuticals collected in DEA authorized collection receptacles (kiosks)
- In both cases, the hazardous waste pharmaceuticals are exempt from RCRA, provided they meet the following conditions:
  - Not sewered, and
  - Managed in compliance with DEA regulations, and
  - Destroyed by a method that the DEA has publicly deemed in writing to meet their non-retrievable standard, or
  - Combusted at one of the following types of permitted facilities
    - Large or small municipal waste combustor (MWC)
    - Hospital, medical and infectious waste incinerator (HMIWI)
    - Commercial and industrial solid waste incinerator (CISWI) or
    - Hazardous waste combustor

§§ 261.7 & 266.507

# NEW EMPTY CONTAINER STANDARDS

| | "RCRA EMPTY" | |
|---|---|---|
| | Non-acute HW Pharms | Acute HW Pharms* |
| Stock/Dispensing Bottles (1 liter or 10,000 pills) & Unit-dose containers | Remove contents | Remove contents |
| Syringes | Fully depress plunger | Fully depress plunger |
| IV Bags | Fully administer contents or § 261.7(b)(1) | Fully administer contents |
| Other Containers | § 261.7(b)(1) or (2) | Can not be RCRA empty |

*No triple rinsing of containers with acute hazardous waste pharmaceuticals

# Shipments of HW Pharmaceuticals

1st Reverse Distributor

2. Potentially Creditable

- Common carrier
- Delivery confirmation

Healthcare Facility

2. Potentially Creditable

1. Non-Creditable

- HW Transporter
- Manifest

2nd Reverse Distributor

3. Evaluated

- HW Transporter
- Manifest

HW TSDF

# DRUG "TREATMENT" SYSTEMS

- There are many brands of "drug treatment" or "drug sequestration" or "drug disposal" devices in use at hospitals
- These units are usually used to collect DEA controlled substances:
  - Use only for disposing "pharmaceutical wastage" of controlled substances
    - "pharmaceutical wastage" does not have to meet DEA's non-retrievable standard of destruction
  - Do not use for disposing inventory of controlled substances

# DRUG "TREATMENT" SYSTEMS

- Odds are these units also have RCRA hazardous waste pharmaceuticals in them
- Thus under Subpart P, these units would be considered hazardous waste pharmaceutical accumulation containers
- The land disposal restriction (LDR) treatment standard for most hazardous waste pharmaceuticals is combustion
- Therefore, the units must be sent to a hazardous waste combustor in order to comply with the LDRs

# CONTACT INFORMATION


- Kristin Fitzgerald — Fitzgerald.Kristin@epa.gov
- Brian Knieser — Knieser.Brian@epa.gov
- Laura Stanley — Stanley.Laura@epa.gov
- Narendra Chaudhari — Chaudhari.Narendra@epa.gov
- Jessica Young — Young.Jessica@epa.gov


Final rule webpage: https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075